cause allergic disease (See for example Allergy 54:103-110 (1999) and J. Clin. Invest. 99(5):879-887 (1997)). In addition, it has been shown that the removal of circulating IgE also causes the downregulation of high affinity IgE receptor expression in patients treated with anti-IgE. (See J. Immunol. 158:1438-1445 (1997)). (These references have been provided for the Examiner's convenience) Thus, it is clear that the antibody has demonstrated utility and therapeutic effectiveness *in vivo*.

In addition, Applicant has shown effective expression and dose dependent expression of anti-IgE. The mouse model used to demonstrate expression of the antibody and the effective reduction of IgE is an accepted model in the field of allergic disease.

Applicant also demonstrated that there was no detectable immune response to the construct even after 58 days of expression.

As for target specificity, IgE is a circulating antibody and therefore the vector need not be present in every cell, nor are there specific cells that need to be targeted.

Applicant has demonstrated stable expression of the encoded gene, a lack of host response to the vector, and a reduction *in vivo* of the IgE levels in an accepted animal model system. It has already been demonstrated that anti-IgE antibodies are an effective therapy for allergic disease. Therefore, Applicant asserts that the teachings of the specification provide sufficient examples and guidance to enable a skilled artisan to practice the invention commensurate in scope of the claims. Therefore, Applicant requests the rejection be withdrawn.

II. Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 17-23 have been rejected as indefinite because it is unclear whether the claims are intended to cover both *in vivo* and *in vitro* methods and/or cells.

Applicant asserts that this rejection is rendered moot by the amendments. The claims were intended to cover only *in vivo* methods. Therefore, Applicant requests that this rejection be withdrawn.

III. Rejection under 35 U.S.C. § 102(e)

Claims 17-21 have been rejected as anticipated by U.S. Pat. No. 6,066,718 (Hardman et al.). In view of the amendments to the claims, Applicant submits that this rejection is now moot since Hardman et al. do not teach *in vivo* methods.

IV. Rejection under 35 U.S.C. § 103(a)

Claims 17 and 23 have been rejected as anticipated by U.S. Pat. No. 6,066,718 (Hardman et al.) in view of U.S. Pat. No. 6,468,547. In view of the amendments to the claims, Applicant submits that this rejection is now moot since Hardman et al. do not teach *in vivo* methods.

Respectfully Submitted,

Dated: September 29, 2003.

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